K091778

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AUG 31 2009

510(k) SUMMARY

VASCUTEK COBRAHOOD™ ePTFE VASCULAR GRAFTS

Date prepared: 12th of June 2009

Prepared in accordance with CFR21 Part 807, Sec. 807.92: Content and format of a 510(k) summary.

Common/Usual Name :	Prosthesis, vascular graft
Proprietary Name(s) :	Vascutek Cobrahood™ ePTFE vascular grafts
Classification Name :	Prosthesis, vascular graft, of 6mm and greater diameter
Classification :	The Food and Drug Administration has classified these devices as Class II devices under classification 21 CFR 870.3450. Classification, DSY.
Applicant and : 510(k) submitter/ contact	Karen Kelso Regulatory Affairs Manager Vascutek Ltd. Newmains Avenue Inchinnan Industrial Estate Renfrewshire, Scotland PA4 9RR, United Kingdom Phone: +44 (141) 814 5527 Fax: +44 (141) 814 3431

Device Predicates:

Predicate Device Names	FDA Clearance Date	Original 510(k)
Vascutek MAXIFLO™ Wrap Grafts		
ePTFE wrapped ePTFE vascular grafts *	14th September 2004	K041528
NOTE: *PTFE external support cleared under K043552 on 5th January 2005 for wrapped grafts (K041528)		
IMPRA Inc. *Distaflo* Bypass Grafts		
ePTFE wrapped ePTFE vascular grafts with flared distal end	24th November 1998	K983861

Device Description:
Vascuteks ePTFE vascular grafts were originally cleared by FDA in 1999 (K992832: unsealed and K993667: gelatin sealed). In 2004, Vascutek received clearance for the application of an external ePTFE wrap to the original FDA cleared ePTFE vascular graft range (K041528). As a result of development in line with design control procedures, it became possible to flare the end of a standard wrapped ePTFE graft to create the Cobrahood™ design as shown in Figures 1a and 1b of this submission. The intended use is, "*bypass or reconstruction of peripheral arterial blood vessels*".

All Vascutek ePTFE grafts are manufactured from virgin expanded polytetrafluoroethylene resin, including the ePTFE external wrap. Cobrahood™ ePTFE vascular grafts are not sealed, i.e. do not have an external gelatin coating. The grafts are available with or without an external support constructed of PTFE. This is identical to the support present on the predicate devices, cleared by FDA in 2005 (K041528).

All Vascutek ePTFE vascular grafts are supplied sterile. The method of sterilization is Ethylene Oxide. A shelf-life of five years has been established. All related parameters remain unchanged to the predicate grafts.

The Cobrahood™ ePTFE vascular graft range is detailed fully in Table 2 of this submission. Manufacturing drawings are provided in Attachment I.

Intended Use:
The subject of this 510(k) is to request FDA clearance for the Cobrahood™ ePTFE vascular grafts, which have the following indication for use;

"*bypass or reconstruction of peripheral arterial blood vessels*".

The Vascutek Cobrahood™ vascular grafts are still intended for prescription use only.

The difference in design of the Vascutek Cobrahood™ vascular grafts, i.e. the presence of the flared outflow is not critical to the intended therapeutic, diagnostic, prosthetic or surgical use of the devices. The difference also does not affect the safety and effectiveness of the device when used as labelled.

Principles of Operation and Technology:
The performance of the Vascutek Cobrahood™ ePTFE vascular grafts remains unchanged. The grafts are still used in surgery in the same manner as standard ePTFE vascular grafts.

Vascutek Cobrahood™ ePTFE vascular grafts are intended only for use in the hospital operating room by suitably qualified surgeons.

Vascutek Cobrahood™ ePTFE vascular grafts are provided sterile by Ethylene Oxide for single use only.

The devices have the same technological characteristics as the predicates i.e. there are no changes to the materials of construction, sterilization, packaging or shelf life.

Performance: The performance of the Vascutek Cobrahood™ ePTFE vascular grafts remains unchanged. The grafts are still used in surgery in the same manner as standard ePTFE vascular grafts.

Bench Testing: For verification purposes, physical testing was undertaken on Cobrahood™ grafts and both predicate grafts, MAXIFLO™ Wrap and Distaflo. All samples tested passed the relevant acceptance criteria. Results have demonstrated that the Cobrahood™ ePTFE vascular grafts are substantially equivalent to the predicate devices.

Clinical Information: No clinical testing has been undertaken on the Cobrahood™ ePTFE vascular grafts, which have been shown to be substantially equivalent to the predicate devices. However, a review of the literature in relation to clinical use of the predicate Distaflo grafts is provided, which has been available commercially in the USA since 1998. It is also demonstrated that clinical use of comparable techniques is an established concept.

Conclusion: In conclusion, the Vascutek Cobrahood™ ePTFE vascular grafts are substantially equivalent to the predicate devices in commercial distribution and results of non-clinical tests and supporting information from the literature demonstrates that the devices continue to be safe, effective and perform as well as the predicate devices.

Substantial Equivalence:
The Vascutek Cobrahood™ ePTFE vascular grafts are substantially equivalent in overall intended use, design and materials, performance, principles of operation and technology to the predicate devices. This is shown comprehensively in Table 2, Section 10 of this pre-market notification.

There are no other design changes to the Vascutek Cobrahood™ ePTFE vascular grafts other than the presence of the flared graft portion.

....12-6-09.....

Signature **Date**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

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Vascutek Ltd.
c/o Dr. Karen Kelso
Regulatory Affairs Manager
Newmains Avenue Inchinnan
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Re: K091778
Vascutek Cobrahood™ ePTFE Vascular Grafts
Regulation Number: 21 CFR 870.3450
Regulation Name: Vascular Graft Prosthesis
Regulatory Class: Class II
Product Code: DSY
Dated: June 12, 2009
Received: June 17, 2009

Dear Dr. Kelso:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091778

Device Name: Vascutek Cobrahood™ ePTFE vascular grafts

Indications For Use: Bypass or reconstruction of peripheral arterial blood vessels

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. McNeil

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K091778